REMARKS/ARGUMENTS

Reconsideration is respectfully requested in view of the amendments and remarks presented herein.

Status of the Claims

Claims 1-28 are pending in the application. Claims 21-28 have been withdrawn from consideration by the Examiner as drawn to non-elected subject matter. It is Applicants' understanding that claims 11-15 and 18 are no longer withdrawn and are under examination.

Discussion of the Amendment to the Claims

The claims have been amended to more particularly point out and distinctly claim the subject matter of the present invention and to advance prosecution. Claims 1 and 11 have been amended to recite that the oral dosage delivery vehicle includes at least one layer of a cast edible film, wherein the active varies no more than 10% among dosage units. Claim 6 has been cancelled in view of the amendment to claim 1. Claims 29 and 30 are newly presented. Support for the amendments to claims 1 and 11 may be found in the application as originally filed at, for example, page 5, paragraph [0026], and at page 10, paragraph [0044]. No new matter has been added by way of the amendments to the claims.

Response to the Rejection under 35 U.S.C. §102(b) in view of Russell

Claims 11-16, 18, and 19 stand rejected under 35 U.S.C. §102(b), as allegedly being unpatentable over U.S. Patent No. 3,444,858 to Russell et al. (hereinafter "Russell"). Reconsideration is respectfully requested in view of the amendments and remarks presented herein.

To advance prosecution, claim 11 has been amended to incorporate the limitation that the active varies no more than 10% among dosage units, as was previously recited in dependent

claim 6, which has not been rejected in view of Russell. Moreover, amended claim 11 recites that the oral dosage delivery vehicle includes at least one layer of a cast edible film. Russell nowhere discloses an oral dosage delivery vehicle, as recited in amended claim 11, having a cast edible film wherein the active varies no more than 10% among dosage units. Indeed, Russell is completely silent with respect to its active varying no more than 10% among dosage units, and provides no disclosure with respect to how to make such a film.

What is not commonly appreciated in the art is that the drying of cast edible films which contain active, such as pharmaceutical actives, must be performed in a manner to maintain uniformity. Conventional drying will not result in uniformity of content, even if the active is uniformly distributed in the film-forming matrix prior to casting. This is due to numerous forces which act upon the active during the casting and drying process. The active is often in particular form and the particles are free to migrate within the matrix in response to thermal and mechanical forces. In such instances migration and/or aggregation of the active occurs, leaving some portions of the cast film with too little active and other portions with too much active. This means that the cast film cannot be precisely cut into equally-sized unit doses which each have the precise amount of active present. The present invention takes advantages of the Applicant's patented process to make the film, which results in uniformity of active content whereby the film can be divided into equal sized dosages which each contain the same amount of active. This is expressed by the amendment which requires that there be no more than 10% variance of active among dosage units. There is nothing in Russell, however, to suggest that its disclosed method of preparing a liquid solution or melt of a gelatinous material and then impregnating the solution or melt with the drug and forming the impregnated solution or melt into a vehicle (*see* column 1, lines 67-71, of Russell) will result in an oral dosage delivery vehicle, as recited in amended claim 11, where the active varies no more than 10% among dosage units. Indeed, Russell merely assumes that its delivery vehicle has been produced so that each section contains a predetermined quantity of drug (*see* column 2, lines 59-61, of Russell). As such, Russell provides no specific

disclosure with respect to the specific amount of drug in each dosage unit, much less any disclosure that the active in its drug delivery vehicle varies no more than 10% among dosage units. Nor is there any disclosure in Russell of the manufacturing steps necessary to overcome the difficulties attendant making a cast film where an active varies no more than 10% among dosage units. Since Russell clearly did not appreciate the problem of making uniform content cast films, it was not possible for him to suggest a solution to the problem. In fact, the problem is complex and the subject of Applicant's prior patented technology.

As Russell fails to disclose every limitation of amended claim 11, Russell fails to anticipate amended claim 11. Claims 12-16 and 18-19 all depend directly or indirectly from claim 11. Accordingly, Russell fails to anticipate claims 12-16 and 18-19 for at least the same reasons discussed with respect to amended claim 11. Indeed, there is no disclosure in Russell of the subject matter of claims 12-16, 18, and 19 as presented herein.

In view of the foregoing, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §102(b) of claims 11-16, 18, and 19 in view of Russell.

Response to the Rejection under 35 U.S.C. §102(b) in view of Fuchs et al.

Claims 1-5, 7-9, and 11-19 stand rejected under 35 U.S.C. §102(b), as allegedly being unpatentable over U.S. Patent No. 4,136,145 to Fuchs et al. (hereinafter "Fuchs"). Reconsideration is respectfully requested in view of the amendments and remarks presented herein.

As amended, claims 1 and 11 recite that the oral dosage delivery vehicle includes at least one layer of a cast edible film, wherein the active varies no more than 10% among dosage units. Fuchs nowhere discloses a cast edible film, let alone a cast edible film wherein the active varies no more than 10% among dosage units. Rather, Fuchs explicitly states that its "films are formed

by drawing . . . rather than by casting or by other known film-forming techniques." (*See* column 3, lines 12-14, of Fuchs). Indeed, the Examiner has acknowledged that the film of Fuchs is drawn. (Office Action, pages 4-5). Moreover, there is no disclosure in Fuchs that its active varies no more than 10% among dosage units. As stated by the Examiner, Fuchs' films can provide for dosage units containing different concentrations of medicaments. (Office Action, page 5; *see* column 3, lines 37-46, and column 4, lines 27-47, of Fuchs).

As Fuchs fails to disclose every limitation of amended claims 1 and 11, Fuchs fails to anticipate amended claims 1 and 11. Claims 2-5 and 7-9 all depend directly or indirectly from claim 1. Accordingly, Fuchs fails to anticipate claims 2-5 and 7-9 for at least the same reasons discussed with respect to amended claim 1. Indeed, there is no disclosure in Fuchs of the subject matter of claims 2-5 and 7-9 as presented herein.

Claims 12-19 all depend either directly or indirectly from claim 11. Accordingly, Fuchs fails to anticipate claims 12-19 for at least the same reasons discussed with respect to amended claim 11. Indeed, there is no disclosure in Fuchs of the subject matter of claims 12-19 as presented herein.

In view of the foregoing, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §102(b) of claims 1-5, 7-9, and 11-19 in view of Fuchs.

Response to the Rejection under 35 U.S.C. §102(b) in view of Mitra

Claims 1-5 and 7-20 stand rejected under 35 U.S.C. §102(b), as allegedly being anticipated by U.S. Patent No. 4,451,260 to Mitra (hereinafter "Mitra"). Reconsideration is respectfully requested in view of the amendments and remarks presented herein.

As amended, claims 1 and 11 recite that the oral dosage delivery vehicle includes at least one layer of a cast edible film, wherein the active varies no more than 10% among dosage units. The Examiner has acknowledged that "Mitra does not teach that the 'active varies no more than 10% among said dosage units.'" (Office Action, page 9). As Mitra fails to disclose every limitation of amended claims 1 and 11, Mitra fails to anticipate amended claims 1 and 11.

Claims 2-5 and 7-10 all depend either directly or indirectly from claim 1. Accordingly, Mitra fails to anticipate claims 2-5 and 7-10 for at least the same reasons discussed with respect to amended claim 1. Indeed, there is no disclosure in Mitra of the subject matter of claims 2-5 and 7-10 as presented herein.

Claims 12-20 all depend either directly or indirectly from claim 11. Accordingly, Mitra fails to anticipate claims 12-20 for at least the same reasons discussed with respect to amended claim 11. Indeed, there is no disclosure in Mitra of the subject matter of claims 12-20 as presented herein.

In view of the foregoing, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §102(b) of claims 1-5 and 7-20 in view of Mitra.

Response to the Rejection under 35 U.S.C. §103(a) in view of Fuchs

Claims 1 and 6 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 4,136,245 to Fuchs (hereinafter "Fuchs"). Reconsideration is respectfully requested in view of the amendments and remarks herein.

As amended, claim 1 requires that the oral dosage delivery vehicle includes at least one layer of a cast edible film, wherein the active varies no more than 10% among the dosage units. Fuchs nowhere discloses or suggests a cast edible film, let alone a cast edible film wherein the

active varies no more than 10% among the dosage units. Rather, Fuchs explicitly states that its "films are formed by drawing . . . rather than by casting or by other known film-forming techniques." (*See* column 3, lines 12-14, of Fuchs). As one of ordinary skill in the art would appreciate, drawing is a completely different manufacturing process from casting and would not be expected to produce films having the same properties as a film which is cast. As such, Fuchs teaches away from the subject matter of amended claim 1. *See* M.P.E.P. §2141.02.VI (internal citation omitted) (stating that "A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention.").

Moreover, there is no disclosure or suggestion in Fuchs that its active varies no more than 10% among dosage units, let alone any teaching or suggestion of how to make a cast edible film where the active varies no more than 10% among dosage units. Rather, Fuchs states that a particular advantage of its invention "lies in the ability with which films can be prepared from a single sheet in which different pharmaceutically active medicaments and/or varying concentrations of active ingredients are incorporated side by side across the width of a drawn web." (*See* Column 4, lines 27-32, of Fuchs). Given this particular advantage and given the explicit disclosure in Fuchs that its films are not formed by casting, one of ordinary skill in the art would have no reason or purpose to make a cast film based on Fuchs' disclosure. Indeed, to do so would be directly contrary to the express disclosure of Fuchs. Moreover, there is no disclosure in Fuchs that the active in its film varies no more than 10% among dosage units, and there is nothing in Fuchs that would suggest to one of ordinary skill in the art that such is the case.

Furthermore, given the inherent difficulties of making a cast film which has less than 10% variance of an active, one of ordinary skill in the art would not expect that such a film could be made with any predictability of results, much less with a reasonable expectation of success based on the disclosure of Fuchs. *See* MPEP § 2143.02.II (stating that "at least some degree of

predictability is required"). This is especially so given that Fuchs provides no guidance as to how to overcome such difficulties and further provides no reason to do so as its films are drawn and not cast.

Applicants thus respectfully submit that amended claim 1 is not obvious in view of Fuchs. Claim 6 has been cancelled. The cancellation of claim 6 renders the rejection with respect to claim 6 moot.

In view of the foregoing, withdrawal of the rejection of claims 1 and 6 under 35 U.S.C. §103(a) in view of Fuchs is respectfully requested.

Response to the Rejection under 35 U.S.C. §103(a) in view of Mitra

Claims 1 and 6 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 4,451,260 to Mitra (hereinafter "Mitra"). Reconsideration is respectfully requested in view of the amendments and remarks herein.

As amended, claim 1 requires that the oral dosage delivery vehicle includes at least one layer of a cast edible film, wherein the active varies no more than 10% among dosage units. Mitra nowhere discloses or suggests an oral dosage delivery vehicle including a cast edible film wherein the active varies no more than 10% among dosage units. Rather, as admitted by the Examiner, "Mitra does not teach that the 'active varies no more than 10% among said dosage units.'" (Office Action, page 9).

Nevertheless, the Examiner has alleged that "it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable amounts or ranges of active ingredient by routine experimentation to obtain the best possible results, as these

are indeed variable parameters attainable within the art." (Office Action, page 9). Applicants respectfully disagree.

As discussed above, there are inherent difficulties in making a cast film where the active varies no more than 10% among dosage units. As Mitra does not disclose that the active in its film varies no more than 10% among dosage units and provides no disclosure with respect to how to make such a film, it cannot be summarily concluded that such a feature is present in the films of Mitra or that it would merely be a matter of routine experimentation to achieve such a film. Indeed, Mitra's disclosure at column 3, lines 63-65, that its device "can be prepared with a known amount of medicament per linear measurement" does not provide any guidance as to how to achieve a cast film having an active which varies no more than 10% among dosage units, much less any predictability of results or a reasonable expectation of success. *See* MPEP § 2143.02.II (stating that "at least some degree of predictability is required").

Applicants thus respectfully submit that amended claim 1 is not obvious in view of Mitra. Claim 6 has been cancelled. The cancellation of claim 6 renders the rejection with respect to claim 6 moot.

In view of the foregoing, withdrawal of the rejection of claims 1 and 6 under 35 U.S.C. §103(a) in view of Mitra is respectfully requested.

Additional Remarks

The Examiner has cited U.S. Patent No. 4,126,503 to Gardner and U.S. Patent Nos. 5,614,212 and 6,024,975 to D'Angelo as allegedly being "pertinent art" which is allegedly "of interest." (Office Action, page 10). Regarding the claims which are under examination, Applicants respectfully note that none of those patents disclose or suggest the subject matter of claims 1-5, 7-20, and 29-30, as presented herein.

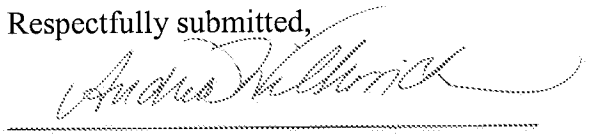
Concluding Remarks

This application is believed to be in condition for allowance. Favorable action thereon is therefore respectfully solicited.

Should the Examiner have any questions or comments concerning the above, the Examiner is respectfully invited to contact the undersigned at the telephone number given below.

The Commissioner is hereby authorized to charge payment of any fees associated with this communication, including any claim fees deemed due for new dependent claims 29-30, or credit any overpayment, to Deposit Account No. 08-2461. Such authorization includes authorization to charge fees for extensions of time, if any, under 37 C.F.R § 1.17 and also should be treated as a constructive petition for an extension of time in this submission or any future submission pursuant to 37 C.F.R. § 1.136.

Respectfully submitted,



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